

REMARKS

Claims 1-20 are pending in the application.

Claims 1-20 have been rejected.

Claims 1, 6-8, 12-17 and 20 have been amended solely to correct informalities.

Claims 4, 9 and 18 have been amended solely to clarify and more distinctly point out the subject matter that the Applicants regard as the invention.

I. **REJECTION UNDER 35 U.S.C. § 102**

Claims 1-3, 6-9, 12-18 and 20 were rejected under 35 U.S.C. § 102(b) as being anticipated by Nita et al. (US 5,951,539). The rejection is respectfully traversed.

A cited prior art reference anticipates the claimed invention under 35 U.S.C. § 102 only if every element of a claimed invention is identically shown in that single reference, arranged as they are in the claims. MPEP § 2131; *In re Bond*, 910 F.2d 831, 832, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990). Anticipation is only shown where each and every limitation of the claimed invention is found in a single cited prior art reference. MPEP § 2131; *In re Donohue*, 766 F.2d 531, 534, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985).

With respect to independent Claims 1, 7 and 13 (and dependent claims), the Office Action argues, without specifically citing portions thereof, that Nita discloses outer and inner insulators fused by heat to each other. To the contrary, Nita discloses:

A shrink wrappable layer of polyethylene tubing is then placed over the tubing and heated so to shrink-wrap the polyethylene and pull the tubing into intimate contact with the reinforcing member (206) winding and perhaps with the inner liner (202). (Emphasis added). Col. 13, lines 9-13.

This passage evidencing that Nita fails to disclose fusing the inner insulator and outer insulator is further buttressed by the following passage in Nita:

As was the case above, it is within the scope of this invention to place an adhesive on the exterior of the assembly at this point to assist in providing adherence of the ribbon (206) and inner liner (202) to the outer polymeric coverings (212, 214, 216, and 218) discussed below. The use of adhesives in this step or in that mentioned above depend principally upon the choice of materials in those outer polymeric coverings. (Emphasis added). Col. 12, lines 38-45.

In view of these passages, it is evident that Nita appears only to recite that the outer polymeric coating is melted (and the shrink-wrap tubing compresses the soft material against the ribbon, and perhaps against the inner insulator), and fails to disclose that the inner and outer insulators are fused together as recited in Applicant's independent Claims 1, 7 and 13.

Moreover, Nita generally describes a catheter having a ribbon (or wire) constructed of a variety of different materials. Metallic and non-metallic ribbons, fibrous materials and elastic alloys may be used. Since these types of materials are disclosed by Nita to construct the ribbon, and furthermore, since Nita fails to address or mention electrical stimulation leads or electrodes, Nita only teaches use of a ribbon for mechanical purposes - strength, torqueability, kink resistance and flexibility. Therefore, Nita's fails to disclose Applicant's "conductor". Nita fails to disclose each and every element/feature as arranged as they are in Applicant's claims.

With respect to dependent Claims 3, 9 and 18 (and claims dependent thereon), Nita fails to disclose a plurality of conductors, and wherein the inner insulator is fused to the outer insulator to electrically isolate each one of the plurality of conductors (or means for conducting)

from one another. Nita fails to disclose this element/feature, while reciting a single ribbon wrapped back upon itself or multiple ribbons that contact each other. See, Figures 2D, 3C, 6-12.

Accordingly, the Applicant respectfully requests the Examiner withdraw the § 102(b) rejection of Claims 1-3, 6-9, 12-18 and 20.

II. REJECTION UNDER 35 U.S.C. § 103

Claims 4-5, 10-11 and 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Nita, et al. (US 5,951,539) in view of Timm, et al. (US 3,760,812). The rejection is respectfully traversed.

In *ex parte* examination of patent applications, the Patent Office bears the burden of establishing a *prima facie* case of obviousness. MPEP § 2142; *In re Fritch*, 972 F.2d 1260, 1262, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention is always upon the Patent Office. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984). Only when a *prima facie* case of obviousness is established does the burden shift to the applicant to produce evidence of nonobviousness. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). If the Patent Office does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of a patent. *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d

1443, 1444 (Fed. Cir. 1992); *In re Grabiak*, 769 F.2d 729, 733, 226 U.S.P.Q. 870, 873 (Fed. Cir. 1985).

A *prima facie* case of obviousness is established when the teachings of the prior art itself suggest the claimed subject matter to a person of ordinary skill in the art. *In re Bell*, 991 F.2d 781, 783, 26 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1993). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed invention and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. MPEP § 2142.

As discussed above in response to the 102 rejection, Nita fails to address or mention electrical stimulation leads or electrodes, and Nita only teaches use of a ribbon for mechanical purposes - strength, torqueability, kink resistance and flexibility. Since Nita teaches the use of non-metallic, fibrous and polymer ribbons, there exists no teaching or suggestion to modify or combine Nita and Timm, as Timm's insulative spacers would provide no benefit to Nita (i.e., no reason to insulate the "conductors" as Nita does not disclose a "conductor"). Moreover, Timm does not appear to disclose an outer insulating material over the conductors. Timm's conductors are exposed and constitute the electrode of the lead (for contact with the tissue).

Furthermore, neither Timm or Nita disclose, suggest or teach fusing of the insulating spacer to the inner or outer insulating material (see, Claims 5 and 11).

As a result, none of the references, either alone or in combination, disclose, teach or suggest Applicant's claimed invention. Nita is directed to a non-electrical catheter, and Timm is directed to exposed conductors of a stimulation lead. Therefore, there is no motivation to combine or modify the references.

Accordingly, the Applicant respectfully requests withdrawal of the § 103(a) rejection of Claims 4-5, 10-11 and 19.

III. CONCLUSION

As a result of the foregoing, the Applicant asserts that the remaining Claims in the Application are in condition for allowance, and respectfully requests an early allowance of such Claims.

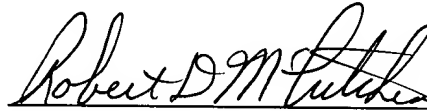
If any issues arise, or if the Examiner has any suggestions for expediting allowance of this Application, the Applicant respectfully invites the Examiner to contact the undersigned at the telephone number indicated below or at *rmccutcheon@davismunck.com*.

The Commissioner is hereby authorized to charge any additional fees connected with this communication or credit any overpayment to Davis Munck Deposit Account No. 50-0208.

Respectfully submitted,

DAVIS MUNCK, P.C.

Date: 10/30/2003



Robert D. McCutcheon
Registration No. 38,717

P.O. Box 802432
Dallas, Texas 75380
(972) 628-3632 (direct dial)
(972) 628-3600 (main number)
(972) 628-3616 (fax)
E-mail: *rmccutcheon@davismunck.com*